

# Successfully Navigating Laws and Regulations

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**Tami L. Wahl**

Special Regulatory Counsel,  
American Herbal Products Association  
[twahl@ahpa.org](mailto:twahl@ahpa.org)

# Scope of this Presentation

- Product classes for Essential Oils
  - Cosmetics
  - Dietary Supplements
- Intended Uses / Claims
- current Good Manufacturing Practices
- Emerging Issues

# Regulation of Essential Oils in the US

- Applicable regulatory framework determined by intended use of product
- Can be a cosmetic or supplement
- Or a food, fragrance, drug, or other consumer product (i.e. candle)

The intended use of the product will determine if an essential oil is a cosmetic or a dietary supplement.



# Intended Uses

- Dietary supplement – statement of nutritional support, structure / function claims
- Cosmetic – to cleanse or beautify a person
- No disease claims!

# Regulation of Supplements in the US

- Must be ingested
- Ingredients
- Dietary supplement forms
- Intended use
- Label / advertising claims
- Good manufacturing practice
- Adverse event reporting

# Regulation of Cosmetics in the US

- Must be intended to cleanse or beautify
- Intended use must not be for a disease condition
- Ingredients in cosmetics
- Label / advertising claims
- Good manufacturing practices
- Adverse event data

# Supplement Claims

21 U.S.C. 343(r)(6)

- ❑ Claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the U.S.;
- ❑ Describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans;
- ❑ Characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function;
- ❑ Describes general well-being from consumption of a nutrient or dietary ingredient.



# Supplement Claims

21 U.S.C. 343(r)(6)

- Must be able to substantiate that such statement is truthful and not misleading
- Required FDA disclaimer
- Issue notification letter to FDA within 30 of launch

# Allowed Supplement Claims 21 CFR 101.93

- Certain OTC drug indications okay as structure/function claims, e.g.:
  - Antacid claims: “For the relief of upset stomach”
  - Sleep aid claims: “For the relief of occasional sleeplessness”
  - Stimulant claims: “Helps restore mental alertness”
  - Laxative claims: “For relief of occasional constipation”

# Unallowed Claims 21 U.S.C. 343(r)(6)

- Any statement that claims to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases – even if truthful and well substantiated.
  - Antacid claims for recurrent or persistent heartburn
  - Sleep aid claims that imply treatment of insomnia
  - Stimulant claims that imply treatment of narcolepsy or chronic fatigue syndrome
  - Laxative claims that are promoted for chronic or persistent constipation
  - Cholesterol-lowering claims

# Example of Supplement Claims

- Acceptable claims for **Valerian**:
  - "...promotes restful sleep."
- Unacceptable claims for **Valerian**:
  - "...for insomnia."
  - "...traditionally used for epilepsy."








# Cosmetic Claims




- Any therapeutic or disease condition claim will move a product from a cosmetic category into a drug category (FD&CA §201(g))
- Any claim with an intended use to cure, mitigate, treat or prevent a disease is a drug claim



# Claims Not Allowed on Cosmetics

-  “ ... erase and repair the ravages of sun damage”
-  “stimulates collagen production”
-  “ ... helps control acne ...”
-  “Calms inflammation and redness”
-  “... help stimulate collagen”

# Allowable Claims on Cosmetics

-  “moisturizing”
-  “make lines and wrinkles less noticeable with moisturizing”
-  “deodorizing”



# Know your ingredients

- Supplements – must be either an “old dietary ingredient” or a “new dietary ingredient”
- Cosmetics – look to CIR / INCI for allowed ingredients, and FDA for a prohibited list of ingredients
- Essential oils – also look to OTC monographs



# Supplement Ingredients

21 U.S.C. 321(ff)(1)

- (A) Vitamins
- (B) Minerals
- (C) Herbs and other botanicals
- (D) Amino acids
- (E) Dietary substances for use by man to supplement the diet by increasing the total dietary intake.
- (F) Concentrates, metabolites, constituents, extracts, or combinations of the above

# Cosmetic Ingredients

- FDA publishes a list of prohibitive ingredients (21 CFR 700)
- Look to Cosmetic Ingredient Review / International Nomenclature of Cosmetic Ingredients
- FDA has premarket approval of color additives (FD&CA §721 (21 USC 379e)), (21 CFR Parts 70, 80)

# Common Notable Violations

- current Good Manufacturing Practices
  - Supplements subject to 21 CFR 111
  - Cosmetics subject to GMP
- Claims / Intended uses
  - On the label
  - Marketing materials / social media, print and online
  - Through consultants







# FDA Inspections

- Quality Control Measures
- Document every step
- Testing
- Possible Outcomes
  - Establishment Inspection Report (EIR)
  - Form FDA-483 Inspectional Observations
  - Warning Letters

# FDA Warning Letters

- Review of these provides excellent “teachings” for industry with respect cGMP compliance and inappropriate claims
- Go to Warning Letters on the FDA Home page ([www.fda.gov](http://www.fda.gov))
- Subscribe to listserv and/or tailor searches

# FDA Warning Letters Inappropriate Claims

-  Aromatherapy products
  -  Website
  -  Social media
  -  Distributors
-  Cosmetics
-  Supplements

# Emerging Issues

- California Proposition 65
- Adverse event data
- Pending cosmetic legislation (S.1014)
- Supply chain interruptions



# SUMMARY

- Consumer safety is primary consideration
- Be reasonable and responsible with claims
  - Truthful and accurate labeling
- Know your product
  - What are the ingredients, safety data
- How is your product manufactured
- No guarantees
  - An action by a regulatory agency or private claimant is always possible
  - Be prepared



# THANK YOU!

**Tami L. Wahl**

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**American Herbal Products Association**

**THE VOICE OF THE HERBAL PRODUCTS INDUSTRY**